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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,082	12/12/2005	Shuji Hinuma	68137(46342)	9415
21874 7590 10/27/2009 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 POSTON, MA 02205			EXAMINER	
			SWARTZ, RODNEY P	
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			10/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/534,082	HINUMA ET AL.			
Office Action Summary	Examiner	Art Unit			
	Rodney P. Swartz, Ph.D.	1645			
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address			
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w.  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on <u>17Jur</u>	ne2009				
	action is non-final.				
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-28,60 and 62-73</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5)⊠ Claim(s) <u>1-9,15,16,24-28,60,62-64,66 and 69-73</u> is/are allowed.					
6) Claim(s) is/are rejected.					
7) Claim(s) <u>10-14,17-23,65,67 and 68</u> is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examine	r.				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
	•				
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal P				
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	6) Other:	atont Application			

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## **DETAILED ACTION**

1. Applicants' Response to Office Action, received 17 July 2009, is acknowledged. Claims 14, 19, 24 and 72 have been amended.

2. Claims 1-28, 60 and 62-73 are pending and under consideration.

## **Rejections Withdrawn**

- 3. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for a period within the claim, is withdrawn in light of the amendment of the claim.
- 4. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite for a period within the claim, is withdrawn in light of the amendment of the claim.
- 5. The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for a period within the claim, is withdrawn in light of the amendment of the claim.
- 6. The rejection of claim 72 under 35 U.S.C. 112, second paragraph, as being indefinite for "pf", is withdrawn in light of the amendment of the claim.
- 7. The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite for dependency from a rejected claim, is withdrawn in light of the amendment of the claim.

## **Double Patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 10 is the peptide, its amide or ester, or salts thereof of claim 1.

9. Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 11 is the peptide, its amide or ester, or salts thereof of claim 6.

10. Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10, 11 and 65. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 12 is the peptide, its amide or ester, or salts thereof of claim 10, 11, or 65.

11. Claim 13 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10, 11 and 65. When two claims in an application are duplicates or else are so close in content that

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they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP  $\S$  706.03(k).

The only component of the medicament of claim 13 is the peptide, its amide or ester, or salts thereof of claim 10, 11, or 65.

12. Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10, 11 and 65. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 14 is the peptide, its amide or ester, or salts thereof of claim 10, 11, or 65.

13. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 15. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the diagnostic agent of claim 17 is the antibody of claim 15.

14. Claim 18 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the diagnostic agent of claim 18 is the antibody of claim 16.

15. Claim 19 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16, 18 or 67. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the diagnostic agent of claim 19 is the antibody of claim 16, 18 or 67.

16. Claim 20 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 15. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 20 is the antibody of claim 15.

17. Claim 21 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 21 is the antibody of claim 16.

18. Claim 22 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 20, 21 or 68. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 22 is the antibody of claim 20, 21 or 68.

19. Claim 23 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 20, 21 or 68. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 23 is the antibody of claim 20, 21 or 68.

20. Claim 65 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 62. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 65 is the antibody of claim 62.

21. Claim 67 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 66. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the diagnostic agent of claim 67 is the antibody of claim 66.

22. Claim 68 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 66. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only component of the medicament of claim 68 is the antibody of claim 66.

## Conclusion

- 23. Claims 10-14, 17-23, 65, 67 and 68 are objected to. Claims 1-9, 15, 16, 24-28, 60, 62-64, 66 and 69-73 are allowed.
- 24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

October 27, 2009